AMENDED IN SENATE AUGUST 23, 2006

AMENDED IN SENATE AUGUST 21, 2006

AMENDED IN SENATE JUNE 27, 2006

AMENDED IN SENATE JUNE 15, 2006

AMENDED IN SENATE MAY 30, 2006

AMENDED IN ASSEMBLY MAY 10, 2005

AMENDED IN ASSEMBLY APRIL 20, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 1062

Introduced by Assembly Member Saldana
(Coauthor: Assembly Member Koretz)

February 22, 2005

An act to amend Section 24173 of, and to add Section 24172.5 to, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1062, as amended, Saldana. Medical experimentation: biomonitoring research informed consent.

Existing law, the Protection of Human Subjects in Medical Experimentation Act, establishes protections for human subjects who participate in medical experiments, including, but not limited to, the requirement of informed consent.

This bill would require that human subjects of biomonitoring experimentation, as defined, be informed regarding, and consent to, the intended use of any biospecimen, as defined, taken from the

subject, be informed, with certain exceptions, regarding the subject's right to review all the laboratory reports and the final research results, and be informed regarding the legal rights that the subject may or may not have regarding any patentable pharmaceuticals or other products that are a byproduct of, or synthesized from, any biospecimen taken from the subject.

This bill would make these provisions inapplicable to clinical trials.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 24172.5 is added to the Health and Safety Code, to read:

24172.5. (a) In addition to the requirements set forth in Section 24172, the subject of biomonitoring experimentation shall be informed and shall consent to all of the following:

(1) The intended use of any biospecimen to be taken from the subject, including, but not limited to, the duration of use, and the disposition of biospecimens when the experiment is completed. If the intended use, duration of use, and disposition of a biospecimen is not known, the subject shall be so informed before the biospecimen is taken.

(2) That, after completion of the study, the subject has the right to review all the laboratory reports and final research results regarding a biospecimen taken from the subject, unless ~~expressly preempted by federal law~~ *otherwise prohibited by federal law or regulation*.

(3) If the Institutional Review Board that approves the study makes a determination, in advance, that the results will not be suitable for release, the subject shall be informed of this determination before the biospecimen is taken.

(b) The subject shall be provided with a written disclosure about any legal rights that the subject may or may not have regarding any patentable pharmaceuticals or other products that are a byproduct of, or synthesized from, any biospecimen taken from the subject.

(c) For the purposes of this section, the following terms have the following meanings:

(1) "Biomonitoring" means the process by which the presence and concentration of toxic chemicals and their metabolites are identified within a biospecimen as a means to assess the chemical body burden.

(2) "Biospecimen" means a sample taken from a biophysical substance, that is reasonably available within a human body, for use as a medium to measure the presence and concentration of toxic chemicals.

(d) This section does not apply to clinical trials.

SEC. 2. Section 24173 of the Health and Safety Code is amended to read:

24173. As used in this chapter, "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172 and Section 24172.5, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not

be informed as to whether they will actually be administered or dispensed a placebo.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars ($10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

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